THE ROLE OF RISK ANALYSIS IN REGIONALIZATION

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Summary: The General Agreement on Tariffs and Trade (GATT) and the establishment of the World Trade Organization (WTO) will radically change the ways in which countries prevent the introduction of exotic animal diseases as a consequence of international trade in animals and animal products. The most important rules are established in the Agreement on Sanitary and Phytosanitary Measures, based on fundamental principles of non-discrimination, harmonisation, equivalence and transparency. These measures require the implementation of regionalization and risk analysis. The Office International des Epizooties (OIE) will play an important role in these developments by establishing internationally accepted standards for these concepts. Slightly distinct, but perhaps not significantly different approaches towards risk analysis and regionalization are emerging. If possible, these approaches must be harmonised. However, most important is the timely collection of the information on which these approaches must be based.

1. DEFINITIONS OF RISK ANALYSIS AND REGIONALIZATION

Risk analysis: the process that includes risk assessment, risk management and risk communication (1). Risk is the likelihood of occurrences and consequences of an adverse event, such as a disease outbreak. Risk assessment is the process of identifying a hazard and estimating the risk associated with the importation of a commodity and evaluating the consequences of taking that risk. Risk management is the identification, analysis, decision and implementation of measures that can be applied to reduce the risks and consequences of an adverse event. Risk communication is the process of communicating the risk assessment results to all possible users (1,9).

Regionalization: recognition of geographical zones of a country that can be identified and characterized by their level of risk for specific diseases. These zones can cover entire countries or parts of countries. Adjacent zones of different countries having similar risk characteristics can be combined into international regions. The region must be clearly and effectively delineated by natural, artificial or legal boundaries. The region must have common control policy for the specific disease. There must be a uniform, effective system of epidemiological surveillance throughout the region. An official sanitary agreement between the countries involved must be in effect (9).

2. GLOBAL ROLE OF RISK ANALYSIS IN REGIONALIZATION

Trade policies for animals, animal products and many other commodities will be guided by international trade agreements according to the rules of the General Agreement on Tariffs and Trade (GATT), the World Trade Organization (WTO) or regional trading blocks such as the North American Free Trade Agreement (NAFTA). The most important agreement in the animal health field is the Agreement on Sanitary and Phytosanitary (SPS) Measures, based on fundamental principles of non-discrimination, harmonization, equivalence and transparency.

Although countries maintain the right to take appropriate measures to protect animal health, it will no longer be justifiable to quote health requirements per se as reasons for non-tariff trade barriers. In this way, trade agreements will depend largely on risk management based on risk assessments that are consistent, transparent and founded on valid scientific evidence. The WTO designated the OIE as the scientific reference body in trade disputes concerning animals and animal products. The OIE may therefore be called on in the future to determine the validity of risk assessments. Consequently, the OIE is in the process of developing international standards, guidelines and recommendations for risk analysis to ensure the harmonization, equivalence and transparency of animal health rules aimed at fair and free international trade in animals and animal products. The OIE published a special issue of the Scientific and Technical Review on risk analysis and animal health and trade (10) that contains several articles covering those subjects. In addition, the 1993 & 1994 up dates of the International Animal Health Code (9) describe detailed procedures recommended for international trade in animals, animal products, animal genetic material, foodstuffs, biological
products and pathological material. There is no doubt that these two OIE publications will greatly stimulate the interest and exchange of information on quantitative risk assessment and regionalization.

3. COUNTRY REPORTS

Reports for the present conference were received from the following OIE Member Countries of the region: Argentina, Canada, Colombia, Cuba, Mexico, Paraguay and the United States of America (USA). Those reports provide clear evidence that regionalization, aimed at preventing the introduction of exotic animal diseases with the least interference to international trade, is of increasing significance in the decision making process of veterinary authorities.

Argentina - The report underlines the need for risk analysis and regionalization for free and fair trade in livestock and livestock products. It indicates that an efficient surveillance and information system of an exporting country is the basic support for risk analysis. The international trade of animals and products of animal origin between countries of different animal disease status must be founded on risk management, based on consistent and well documented scientific evidence. The report describes the methodology that Argentina is applying and includes a list of events that can be used to evaluate the presence of the pathogen and those to estimate the probability of transmission or survival of the agent. The report further discusses some of the considerations for regionalization, and aspects to be carefully thought about in making a risk analysis.

Canada - Regionalization is not a new idea in Canada in facilitating the international movement of livestock and livestock products. For instance, regionalization of bluetongue in the Okanagan Valley of British Columbia kept the European market open for trade in livestock and livestock products. Regionalization of brucellosis and tuberculosis facilitated the export of cattle to the USA. For imports, Canada accepts the regionalization of bluetongue in the Australia and the USA. The report stresses the importance of competent veterinary services, control of livestock movement and disease surveillance, including adequate diagnostic laboratory facilities. Also, an exporting country must have a favourable history of international reporting of animal diseases. Establishment of international standards for regionalization according to the OIE principles are essential. Risk assessment must be the basis for the decision-making process, taking into account country, commodity and exposure factors. However, the establishment of international standards and the active participation of trading partners are fundamental.

Colombia - The report emphasizes the need to establish areas free of specific diseases. The "disease-free zone" concept includes the evaluation of the risks of re-introduction of disease agents into the free areas. These risks depend on the epidemiology of the disease, the disease situation of adjacent zones or provinces and the preventive measures used. The report, furthermore, stresses the need to analyse risk according to uniform standards and considers that the OIE Regional Commission for the Americas must take the lead in this harmonization.

Cuba - The country uses risk management in the seaports and airports with international activities. Its authorities have requested the assistance of the Pan American Foot-and-Mouth Disease Center ("Panaftosa") for practical training in the application of quantitative assessment.

Mexico - The report indicates that the country presently considers the regionalization concept an important tool in facilitating international trade in livestock and livestock products. The use of this tool implies the application of risk analysis. It includes evaluation of the Veterinary Services of the exporting region, an analysis of the possibilities of introduction or re-introduction of a disease and of animal movement in and out of the region.

Paraguay - The report recognizes regionalization and risk analysis as important tools in facilitating international trade of animals and products of animal origin. The criteria for specific risk evaluations, as well as sanitary requirements, must be taken into account the recommendations of the International Animal Health Code of the OIE.

United States of America - The USA report briefly describes risk analysis (i.e. risk assessment, risk management, and risk communication) methodologies. Risk analysis and regionalization are tools for evaluating scientific information and for establishing geographic areas which are identified and characterized by their risk levels for specific diseases. Risk assessment may be either qualitative or quantitative, the latter being a probabilistic approach. Evaluations of the effectiveness of the both veterinary infrastructure and disease surveillance, and the reliability of information are important considerations in both approaches. The ultimate decision of what level of risk is acceptable to the importing country must be based on a cost/benefit analysis.

4. DEVELOPMENTS IN THE AMERICAN REGION
On 18 March 1994, the OIE Regional Commission for the Americas recommended that the countries of the Region begin progressively using quantitative risk analysis to make decisions concerning the importation of livestock and animal products, based on the standards described in the *International Animal Health Code* (9). The Regional Commission further recommended that the staff of the Veterinary Services of Member countries be trained in the methodologies of risk analysis, evaluation of veterinary services and regionalization. The country reports show that the awareness of those needs is well recognised throughout the region. Professionals of individual countries, as well as international organisations such as the Pan American Health Organization (PAHO) through its Pan American Foot and Mouth Disease Center (Panaftosa), have been active in these aspects. The staff of the Animal Plan Health Inspection Service (APHIS) of the US Department of Agriculture prepared a comprehensive list of risk assessments (3) that provides a synopsis of work in progress and of ongoing activities, with the goal of stimulating and encouraging discussion on risk assessment. Panaftosa applied risk assessment methodologies to its specialised field and held several training workshops/seminars on the subject in the Caribbean and in Latin America.

In view of the GATT and WTO agreements, APHIS/USDA developed, within the framework of the *International Animal Health Code* of the OIE (9), a set of general criteria for the regionalization of levels of risk for countries or regions with different disease status (2).

Presently, the USA applies the Tariff Act, adopted by Congress in 1930, to prohibit the import into the USA of ruminants and pigs and their meat from countries infected with foot and mouth disease (FMD), except when those products have been treated by heat and other methods which destroy the FMD virus (7). Countries may be considered free from FMD provided that FMD has not occurred for at least one year, that vaccination is not used, and that importation of animals and animal products are strictly regulated. All countries of Central America and Mexico have regulations similar to those of the USA. The terms "disease free" and "not free" must be redefined for regionalization criteria as proposed by APHIS (2). A "disease free" zone would not be risk free, while "not free" would not automatically imply an absolute likelihood of failure. Risk levels are expressed as an abstract number (probability of failure) varying from approaching zero to approaching one, but never quite reaching either zero or one. Within that range the proposal recognises 6 risk levels: RN, R1, R2, R3, R4 and RU, where RN means "negligible Risk" and RU is "unknown risk". These are the zones with the lowest and highest risk levels, respectively. Between those extremes are R1 → R4, showing increasing levels of risk.

For the purpose of this report, the criteria for the animal disease regionalization, as presented by APHIS/USDA, were tabulated in abbreviated form under the following headings: prevalence of the agent, vaccination policy, objectives of the disease prevention or control program, and contacts with other (border) regions, as shown in Table 1.

In order for a region to be classified as having "negligible risk" for a specific disease, the causal agent must not have been diagnosed within the region during the lifetime of any currently living susceptible animal. At the low and moderate risk levels the disease must not have occurred within the past year and the maximum annual herd incidence over the past 5 years must be less than 0.1%; however, there is no mention of the type of agent. Vaccination must be prohibited in lower risk classes, but exceptions may be made for certain diseases such as vector transmitted diseases or animals specifically vaccinated to meet the import requirements of other regions. There must be adequate policies and infrastructure in place to respond to the program objectives. Regions of different risk levels must be separated by natural or man-made barriers. Where mentioned in Table 1, all border access points must be strictly controlled to prevent movement of susceptible animals or animal products from adjacent regions except under approved conditions. Conditional import into the region must be conducted under conditions which are equivalent to those required by the USA for export from countries with a similar disease status.

Risk management of commodities could vary from a simple certification of origin for products coming from low risk zones to high security quarantine for importations originating from high risk zones. By developing this regionalization strategy it would be feasible to recognise zones of a country as having a low risk level while other parts of the country may be at higher risk. Adjacent zones of neighbouring countries with similar risk levels could be combined into international regions. Obviously, the classification of zones or regions according to their risk level would have to be transparent and well documented. Risk assessment for livestock or animal products and the risk level of the zone or region of origin would determine the import risk of that product and the effectiveness of eventual risk reduction measures. However, the determination of acceptable risk would ultimately be based on the benefits vs. costs of success or failure in assuming the risk.

### Table 1

<table>
<thead>
<tr>
<th>Summary of general criteria for animal disease regionalization*</th>
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<tr>
<td>Prevalence of Agent</td>
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<td>---------------------------------------------------------------</td>
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</table>

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| RN (negligible) | Not diagnosed within lifetime of species | Prohibited during lifetime of any currently living animal | Passive surveillance. Emergency preparedness | Agent not known to exist in adjacent regions. Border control R1, R2. Import conditional for R1, R2, R3, R4, RU. |
| R1 (very low) | Not diagnosed within past 5 years | Prohibited Elim. of all previously vaccinated animals | Passive and active surveillance. Emergency preparedness | Border control for R2, R3, R4, RU. Import conditional for R2, R3, R4, RU |
| R2 (low) | Not diagnosed within past year. Maximum annual herd incidence past 5 years less than 0.1% | Prohibited or limited to herds at risk | Passive and active surveillance. Emergency preparedness | Border control for R3, R4 RU. Import conditional for R3, R4, RU |
| R3 (moderate) | Diagnosed within past year. Maximum annual herd incidence past 5 years not exceeding 0.1% | Limited to herds at risk | Passive and active surveillance. Elimination of outbreaks | Border control for R3, R4 or RU Import conditional |
| R4 (high) | Diagnosed annual herd incidence past 5 years may have exceeded 0.1% | Widely practised | Passive and active surveillance. Restriction of outbreaks | |
| RU (unknown) | Unknown | | | |

* APHIS/USDA (2).

Within its field of expertise, Panaftosa has applied risk assessment methodologies to FMD. Some of the assessments were mostly qualitative: for example, the study by Astudillo et al. (4) on the prevention of reintroduction of FMD in Chile. Other risk assessments were more quantitative. For instance, at the request of the Caribbean countries, a study was made on the risk of importation of meat from selected regions of Argentina and Uruguay (12). That study used a stochastic model based on the epidemiological behaviour of the disease in the South American countries. It covered disease prevalence and the capability of the animal health surveillance system to detect the disease at the source of the products, as well as during the transportation of the animals to the slaughter plant. It also covered the efficacy of ante- and post-mortem examinations. Finally, the model took account of the probability that FMD virus may survive deboning, chilling and processing. Under the auspices of Panaftosa, Sutmoller and Wrathall (13) studied the risk of FMD transmission by bovine embryo transfer. In a further study, those authors compared the risk of FMD, bluetongue and vesicular stomatitis (14).

In both models, emphasis was placed on disease prevalence, the efficacy of the animal health surveillance system and the competence of the embryo collection team. These risk analysis studies depended directly on the information generated by the Continental Vesicular Disease Surveillance and Information System in South America, coordinated by Panaftosa (5). This system is composed of a network of national disease surveillance systems that report epidemiological information on weekly basis. Panaftosa compiles this information and reports back to the countries by means of weekly and monthly epidemiological bulletins (11). In the event of an emerging epidemiological problem, communication is immediate. The National Vesicular Disease Surveillance Systems use the existing animal health infrastructure, including over 2 600 local field units of the national FMD control and eradication programs. In addition, there is an effective participation of the private sector, particularly of the livestock industry. The geographical coverage of each field unit is represented by a quadrant of the country's map according to geographical coordinates (5,6). Each
The Continental Vesicular Disease Surveillance and Information System has provided up-to-date epidemiological information on the behavior of FMD in the field and alerted veterinary authorities to the development of higher risk situations and emerging problems. The information collected allowed the timely evaluation and orientation of animal health strategies for a more effective and efficient control and eradication of FMD. The system was also the foundation for the characterization and regionalization of ecosystems of FMD endemism. This FMD regionalization in South America has evolved over the past 20 years (10) and was instrumental in the development of regional strategies for the eradication and control of FMD.

This same methodology provides an excellent opportunity for a risk regionalization for livestock and livestock products, that in principle would be similar to the proposed APHIS/USDA program (2), but obviously would be more disease specific. In Table 2, the letters A, B, C and D denote the different risk levels, where A indicates the lowest FMD risk for an importing country, and D the highest risk.

Table 2

South America foot and mouth disease risk classification

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Frequency of FMD</th>
<th>Viral activity</th>
<th>Vaccination</th>
<th>Program objectives</th>
<th>Border region</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>&gt;5 years no FMD</td>
<td>No</td>
<td>No</td>
<td>Prevention</td>
<td>A2, B1, B2</td>
</tr>
<tr>
<td>A2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C*, D*</td>
</tr>
<tr>
<td>B1</td>
<td>&gt;2 years no FMD</td>
<td>Neg**</td>
<td>Yes</td>
<td>Eradication and</td>
<td>B2, C, D*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>prevention</td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>1-2 years no FMD</td>
<td>??</td>
<td>Yes</td>
<td></td>
<td>C, D*</td>
</tr>
<tr>
<td>C</td>
<td>Sporadic</td>
<td>Yes</td>
<td>Yes</td>
<td>Advanced control</td>
<td>D</td>
</tr>
<tr>
<td>D</td>
<td>Endemic</td>
<td>Yes</td>
<td>Yes</td>
<td>Control</td>
<td></td>
</tr>
</tbody>
</table>

* Require effective natural or man-made barriers
** According to serological and virological surveys

The main considerations for the Panaftosa risk regionalization are the time periods during which clinical cases are absent, the presence or absence of FMD viral activity, and whether or not FMD vaccination is used. A non-vaccinated, fully susceptible livestock population guarantees the absence of any occult viral activity. In the A1 and A2 risk level regions FMD must not have occurred for at least five consecutive years and vaccine must not have been used for at least one year. A FMD prevention program, including import controls, must be in operation. The next consideration is the FMD situation in the surrounding regions. For instance, A2 level regions are those A regions which border regions classified as C or D. Therefore, to prevent disease introduction, those A2 regions will likely have to be separated from the C or D level regions by natural or man-made barriers. These regions must maintain a strong, active vesicular disease surveillance, particularly in the border areas.

The objectives of the FMD program in B risk level regions are eradication and prevention, but vaccination is used to control the disease. B1 level regions must have been free from FMD for at least two years and in B2 level regions this period is set between one and two years. In order for a region to be classified as B1, there must be sufficient evidence, through survey methods or otherwise, to demonstrate the absence of viral activity in the livestock population. C risk level regions have only sporadic cases of FMD and advanced control programs aimed at eradication must be present. Regions classified as D are those in which FMD is endemic and where there is a control program. Of course, the proposed classification is based on present data and regionalization is a continuous dynamic process. For example, Paraguay has not registered any cases of FMD over the past year, and therefore its classification changed to a lower risk category a few months ago.

The map in Figure 1 illustrates the present regionalization: the south of Chile, Patagonia, Surinam, French Guyana and Uruguay are in the A1 risk level. Guyana, the Chocó region in the northwest of Colombia and the north of Chile are classified as A2, but large parts of South America, with a majority of the best cattle-raising regions, are classified as B. The B1 risk level regions, which have been without FMD for more than two years, include the Argentine province of Mesopotamia, while the B2 level regions, where FMD has not occurred during the last 1-2 years, cover the rest of Argentina, Paraguay, and the States of Rio Grande do Sul and Santa Catarina of Brazil; the remaining parts of the continent are in either the C or D risk levels. Thus, according to this risk regionalization, important livestock regions of
South America are in the lowest categories with over 90 million head of cattle, some 40 million sheep and 10 million swine.

5. DISCUSSION AND CONCLUSIONS

In the present developmental stage it is not surprising that slightly different approaches towards risk analysis and regionalization are emerging. The first one was advanced by Morley & Acree (8). They defined unrestricted import risk as the product of the probability of agent entry and the probability of livestock exposure in the importing country. The probability of agent entry is a function of the country factor (prevalence of List A or List B diseases (9) and evaluation of the Veterinary Services of the exporting country), the commodity factor (species, age and breed of animals, diagnostic tests, stability of the agent, etc.) and the number of Animal Import Units. The probability of exposure in the importing country is the likelihood that the agent infects and spreads throughout a susceptible population in the importing country. The unrestricted risk can be mitigated by risk reduction measures. This approach was summarized in the Guidelines for risk assessment in the 1993 & 1994 Updates of the International Animal Health Code (8). Variants on these guidelines have been used for individual risk assessments using scenario trees or pathways (3,8,12,13,14). Using this method, for each individual analysis a pathway of potential risk events is traced from the point of origin of the product to its final destination. For each event in the scenario pathway the following questions are asked: "What can go wrong?", "How often is this likely to happen?", and "What will be the consequences?" (10). Accumulation of quantitative answers to these questions for all the events in the pathway constitutes the measure of risk related to the importation. The great advantage of the scenario tree or pathway model is that it permits clear presentation of the country and commodity factors with regard to quantification and documentation.

The OIE guidelines (9) for regionalization define disease free zones, with or without vaccination, infected zones, surveillance zones and buffer zones. The APHIS proposal for regionalization quite precisely characterizes and redefines "disease free" and "not free" in terms of levels or degree of risk. Within each risk level, risk assessments can be made for different commodities and risk reduction measures can be used to reach a level of acceptable import risk. The Panaftosa risk regionalization is a variant of the APHIS proposal, but is specific to the FMD situation in South America. For instance, it includes the category "viral activity". The level of sophistication of the Panaftosa regionalization is a reflection of the reliability and detailed character of epidemiological information generated by the Continental Vesicular Disease Surveillance and Information System.

The final decision on the acceptable level of risk by the importing country is made by taking a risk-related cost-benefit analysis into account.
Figure 1
Risk regionalization of foot and mouth disease in South America - September 1995
REFERENCES


11. Pan American Foot and Mouth Disease Center (PAHO). Weekly and monthly epidemiological reports. PAHO, Rio de Janeiro, Brazil.

